

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
<hr/>		
THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8514

Bartle, C.J.

August 19, 2010

Judith L. Watts ("Ms. Watts" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Irvin F. Goldenberg, M.D., F.A.C.C. Based on an echocardiogram dated October 7, 1997, Dr. Goldenberg attested in Part II of claimant's Green Form that Ms. Watts suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.³ Based on such

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Goldenberg also attested that claimant suffered from New York Heart Association Functional Class II symptoms. This condition, however, is not at issue in this claim.

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$491,142.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Abdel M. Ahmed, M.D., F.A.C.C., stated that claimant had "2+ mitral insufficiency." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2003, the Trust forwarded the claim for review by David M. Kerins, M.D., F.A.C.C., F.A.H.A., F.E.S.C., one of its auditing cardiologists. In audit, Dr. Kerins concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation.⁵ In support, Dr. Kerins explained that:

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Although he initially concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation, Dr. Kerins subsequently submitted a declaration dated December 10, 2003 wherein he stated that his
(continued...)

The study of 10-7-97 revlealed [sic] mild mitral regurgitation with a RJA/LAA ratio of 15%, the second study from 10-14-98 revealed slightly more mitral regurgitation with a RJA/LAA that barely exceeds 20%. Of note, reports are provided for 2 subsequent echocardiograms on 11-2-2000 which reported trivial to mild Mitral Regurgitation and on 2-7-2002 that reported no significant insufficiency.

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying this claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that there was a reasonable medical basis for the attesting physician's representation that Ms. Watts had moderate mitral regurgitation. In support, claimant submitted a report from Dr. Goldenberg wherein he stated:

Mitral regurgitation severity was determined in the four chamber apical view on multiple

5. (...continued)

earlier "opinion was not stated correctly" and asked that his Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue dated August 18, 2003 be amended to reflect his opinion that there was "no reasonable medical basis" for the attesting physician's finding of moderate mitral regurgitation. On December 29, 2003, an amended Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue was issued.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the claim of Ms. Watts.

beats using the [Green Form and Settlement Agreement] guidelines and criteria. However in order to avoid any chance of an overestimation of the regurgitant ratios all left atrial areas were generously traced to assure that left atrial areas were clearly the maximum left atrial size (Left atrial area) for that given frame.

Despite generously measuring the left atrial size (which favors smaller RJA/LAA ratios) we still clearly showed that this [claimant] had moderate mitral regurgitation

Dr. Goldenberg attached a number of still frames from claimant's echocardiogram that he said demonstrated moderate mitral regurgitation. In addition, claimant contended that Audit Rule 5 permitted Dr. Kerins to find mild mitral regurgitation while concluding that there was a reasonable medical basis for the attesting physician's Green Form representation of moderate mitral regurgitation. Ms. Watts also submitted that an October 14, 1998 echocardiogram supported Dr. Goldenberg's conclusion that claimant had moderate mitral regurgitation.⁷

7. Claimant also argued that the Trust should not be allowed to rescind its original post-audit determination because: (i) rescission is not permitted under the Audit Rules; (ii) the Trust did not have authority to change the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue completed by Dr. Kerins; and (iii) claimant relied upon the audit determination in seeking Matrix Benefits. Dr. Kerins, however, submitted a declaration dated December 10, 2003 wherein he stated that the initial Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue did not correctly reflect his opinion. Dr. Kerins concluded that there was, in fact, no reasonable medical basis to support a finding of moderate mitral regurgitation based on claimant's October 7, 1997 echocardiogram, and requested that his earlier Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue be amended to reflect his actual opinion. We reject claimant's
(continued...)

The Trust then issued a final post-audit determination, again denying this claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On November 17, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4142 (Nov. 17, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 26, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a

7. (...continued)

argument that an auditing cardiologist is not allowed to correct a misstatement in connection with his or her audit of a claim for Matrix Benefits.

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination.

See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Watts reasserts the arguments she made in contest; namely, that there is a reasonable medical basis for Dr. Goldenberg's finding that claimant had moderate mitral regurgitation. Additionally, claimant contends that Dr. Goldenberg's report includes specific measurements, calculations, and still frames demonstrating moderate mitral regurgitation in at least four cardiac cycles. Finally, claimant suggests that Dr. Kerins changed his initial opinion "[u]ndoubtedly at the urging of the Trust."

In response, the Trust argues that the audit was conducted in accordance with the terms of the Settlement Agreement. The Trust also counters that Dr. Kerins was not coerced to change his response on the audit report to indicate that there is no reasonable medical basis for Dr. Goldenberg's representation of moderate mitral regurgitation. The Trust contends that the initial report was rescinded because of an error, not because of a change of opinion. According to the Trust, Dr. Kerins never wavered on his conclusion that claimant's echocardiogram of attestation demonstrated "mild mitral regurgitation with a RJA/LAA of 15%."

The Technical Advisor, Dr. Vigilante, reviewed claimant's October 7, 1997 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

A thin jet of mitral regurgitation was noted in the parasternal long axis view. Only mild mitral regurgitation was present on this study of October 7, 1997. I digitized those cardiac cycles in which the mitral regurgitation appeared most impressive in the apical two chamber and apical four chamber views. I then measured the RJA and LAA in these cardiac cycles. The RJA/LAA ratio was less than 10% in the apical two chamber view. The mitral regurgitation was most impressive in the apical four chamber view. However, even in those views in which the mitral regurgitation appeared the worst, the RJA/LAA ratio was less than 14%. The RJA/LAA ratio never approached 20%. I reviewed the photographs and measurements of the mitral regurgitation taken by the Attesting Cardiologist. The true LAA was slightly

larger than those measurements which he made. However, the biggest error was in the measurement of the RJA's. Dr. Goldenberg incorporated non-mitral regurgitant low velocity flow in his measurements of the RJA....

* * *

In response to Question 1, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of October 7, 1997 demonstrated only mild mitral regurgitation with comments as above. The RJA/LAA ratio never approached 20%. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.'

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Vigilante. Specifically, Ms. Watts does not challenge Dr. Vigilante's conclusion that "the echocardiogram of October 7, 1997 demonstrated only mild mitral regurgitation," and that "[t]he RJA/LAA ratio never approached 20%."¹⁰ On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also reject claimant's argument that Dr. Goldenberg's opinion and the still-frame images included with

9. Dr. Vigilante also reviewed claimant's echocardiogram of October 14, 1998, and determined that "[t]he RJA/LAA ratio was less than 19% in those views in which the mitral regurgitation appeared most impressive."

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

claimant's contest materials provide a reasonable medical basis for Dr. Goldenberg's Green Form representation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Vigilante found that claimant's attesting physician improperly measured her level of mitral regurgitation. Specifically, Dr. Vigilante concluded that Dr. Goldenberg improperly "incorporated non-mitral regurgitant low velocity flow in his measurements of the RJA." Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of this claim for Matrix Benefits.